NDA 050722/S-056, S-058
NDA 050723/S-056, S-058
NDA 050758/S-054, S-056
NDA 050759/S-063, S-065

SUPPLEMENT APPROVAL

Hoffman-La Roche, Inc.
c/o Genentech, Inc.
Attention: Elizabeth Wishart
Regulatory Agent
1 DNA Way
South San Fransisco, CA 94080

Dear Elizabeth Wishart:

Please refer to your supplemental new drug applications (sNDAs) dated and received June 16, and July 27, 2026, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA Number	Drug Name
50722	CellCept (mycophenolate mofetil) capsules, 250mg
50723	CellCept (mycophenolate mofetil) tablets, 500mg
50758	CellCept (mycophenolate mofetil hydrochloride), intravenous
50759	CellCept (mycophenolate mofetil), oral suspension

These Prior Approval sNDAs provide for edits to the approved CellCept labeling to remove text regarding the Mycophenolate Risk Evaluation and Mitigation Strategy (REMS) and proposed modifications to the approved Mycophenolate Shared System (SS) REMS. These supplements are in response to our June 2, 2026, REMS Modification Notification letter.

APPROVAL & LABELING

We have completed our review of these supplemental applications. They are approved effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENT

The SS REMS for Mycophenolate, of which Cellcept (mycophenolate mofetil) is a member, was originally approved on September 25, 2012, and the most recent REMS

modification was approved on August 13, 2024. The SS REMS consists of elements to assure safe use, and a timetable for submission of assessments of the REMS.

Because we determined that a REMS is no longer necessary to ensure the benefits of mycophenolate outweigh its risks, you were required to submit a REMS modification to eliminate the REMS as outlined in our REMS Modification Notification letter dated June 2, 2026.

Elements to Assure Safe Use: We have determined that the elements to assure safe use are no longer necessary because a REMS is no longer necessary to ensure the benefits of the drug outweigh the risk of embryofetal toxicity associated with the use of mycophenolate during pregnancy based on the following data:

- An analysis of mycophenolate prescription utilization patterns from US outpatient retail and mail order pharmacies from 2012 through 2023 indicates that prescribing behavior is more cautious in females 10 – 54 years of age;

- An analysis of females 10 – 54 years of age with a pregnancy outcome from 2013 through 2024 in the Sentinel Distributed Database (SDD) that confirmed the following:

    - a low prevalence of mycophenolate use during pregnancy;

    - lower mycophenolate use during pregnancies in the organ transplant and off-label indication cohorts compared to their respective matched nonpregnant cohorts;

    - the majority of pregnancy episodes associated with mycophenolate use started within the 183-day pre-pregnancy period did not continue mycophenolate during the pregnancy.

Therefore, because the elements to assure safe use are no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for mycophenolate.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for

the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your supplemental application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[1]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[2] Information and Instructions for completing the form can be found at FDA.gov.[3]

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Susie Choi, Safety Regulatory Project Manager, at 240-402-2925.

Sincerely,

{See appended electronic signature page}

Hyon Kwon, PharmD, MPH
Deputy Director for Safety
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

HYON J KWON
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